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| 10/686,517 | 10/16/2003 | Amar Lulla | 33396-198024 | 4905 |
| 26694 | 7590 | 09/28/2007 | EXAMINER | |
| VENABLE LLP | | | YOUNG, MICAH PAUL | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/686,517 | Applicant(s) LULLA ET AL. | |
| | Examiner Micah-Paul Young | Art Unit 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,8,10-12,14,15,17-20,22,23,25,26,28,29,31-33,35-40,44,74 and 75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1-4,6,8,10-12,14,15,17-20,22,23,25,26,28,29,31-33,35-40,44,74 and 75.

DETAILED ACTION

Acknowledgement of Papers Received: Amendment/Response dated 7/2/07.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1,10,17,18,35,74 and 75 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Biedermann et al (USPN 5,980,921 hereafter '921). The claims are drawn to a spray composition for topical application comprising at least one medicament, at least one film forming polymer, at least one vehicle and at least one of the following: at least one stabilizer, permeation enhancer, solubilizer, plasticizer and a water-soluble additive.

3. The '921 patent teaches a topical composition comprising a an active agents (present in a concentration from 3-5%), film-forming polymer (pvp) and vehicle (water) along with a

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plasticizer (dimethyl isosorbide) (from 5-20%) (Abstract, col.4, lin. 38-44, col. 5, lin. 20-25, 60-65, col. 9, lin. 29-44, and col 10, lin. 17-25). The compositions are sprayed onto the skin and are intended to stay put providing a stable film that is water resistant (col. 14, lin. 30-38; examples). The active agents include anti-inflammatory agents such as hydrocortisone (col. 11, lin. 1-46).

4. Regarding the stable, breathable film limitation it is the position of Examiner that such limitations are inherently taught and possessed by the prior art product. The prior art teaches a topical sprayed composition comprising the same components in identical concentrations as the instant claims. The foams created by the '921 patent are stable and porous allowing for air transfer. Since the prior art teaches the same components combined in the same way in the same concentration, it remains the position of the Examiner that the composition of the '921 would inherently possess each and every property of the instant claims barring a showing to the contrary.

5. For these reasons at least the instant claims are anticipated.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4,6,8,10-12,14,15,17-20,22,23,25,26,28,29,31-33,35-40,44 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Osipow et al (USPN 4,328,319 hereafter '319).

The claims are drawn to a spray composition for topical application comprising at least one medicament, at least one film forming polymer, at least one vehicle and at least one of the following: at least one stabilizer, permeation enhancer, solubilizer, plasticizer and a water-soluble additive.

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7. The '319 patent teaches a topical spray formulation containing an active agent, a film forming synthetic layer, a vehicle and other carriers, wherein the composition is made into a stable foam composition useful in external application (abstract, col. 11, lin. 57-col. 12, lin. 38).

8. Regarding claims 2,3,12,14,15,17-19 and 37-39, it is the position of the Examiner that the disclosures of the '319 patent anticipate the claims. The '319 patent teaches various medicaments such as steroids and hormones (hydrocortisone or testosterone) in a concentration from 0.02-15% (col. 12, lin. 1-38).

9. Regarding claims 4,31,32,37,40 and 45, it is the position of the Examiner that the disclosures of the '319 patent anticipates the claims. The '319 patent teaches film forming polymers (e.g. alkyl acrylate and alkyl methacrylate polymers and copolymers or ethyl cellulose), where the composition contains the said polymers up to 50% by weight (col. 8, lin. 54-col. 9, lin. 20 and lin. 64-66).

10. Regarding claims 6,8,10,11,20,22,23,28,29,33,35-37,40 and 44 it is the position of the Examiner that the disclosures of the '319 patent anticipates the claims. The '319 patent teaches a permeation enhancers (e.g. surfactants or oleic acid, 0.0001-8%) (col. 7, lin. 5-31); plasticizers (e.g. citrate esters such as tributyl citrate, 0.0001-10%) (col. 10, lin. 60-col. 11, lin. 11); propylene glycol (humectant), water as a vehicle, sodium lauryl sulphate as a solubilizer (col. 8, lin. 15-32 and col. 7, lin. 6 and lin. 55-69).

11. Regarding claims 25 and 26, which further limit the propellant, the '319 patent teaches a propellant at a concentration from 20-70% such as P114, P22 (col. 9, lin. 20-67 and col. 10, lin. 3-7).

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12. Regarding the stable, breathable film limitation it is the position of Examiner that such limitations are inherently taught and possessed by the prior art product. The prior art teaches a topical sprayed composition comprising the same components in identical concentrations as the instant claims. The foams created by the '319 patent are stable and porous allowing for air transfer. Since the prior art teaches the same components combined in the same way in the same concentration, it remains the position of the Examiner that the composition of the '319 would inherently possess each and every property of the instant claims barring a showing to the contrary.

13. For these reasons at least the instant claims are anticipated.

Response to Arguments

14. Applicant's arguments with respect to claims 1-4,6,8,10-12,14,15,17-20,22,23,25,26,28,29,31-33,35-40,44,45,74 and 75 have been considered but are moot in view of the new ground(s) of rejection. However the '319 patent remain an anticipatory reference. Applicant has argued that the foams of the '319 patent though comprising the same components at the same concentrations would not produce "stable, breathable foams". It is the position of the Examiner that the foams of the '319 patent would constitute a film of material applied to the skin. Their stability is disclosed in the prior art patent as being not spreadable after spaying (col. 15, lin. 1-15). Applicant describes a stable film as such in the specification. Further applicant describes the films must also be applied and left for an extended period of time. Again the '319 foams are intended for extended application (col. 15, lin. 1-10). Though the sprays of the prior art produce foams and not specifically the "films" of the instant invention, they fulfill the same

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purpose and meet the limitations of the instant invention. Also applicant has not defined the films of the instant invention by thickness or constitution, beyond their stability. The products of the '319 patent are stable, and breathable by virtue of the porous foam nature. Applicant has provided no differentiating disclosures that would distinguish the "films" of the instant claims from the foams of the prior art other than semantics. For these reasons the claims remain rejected.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

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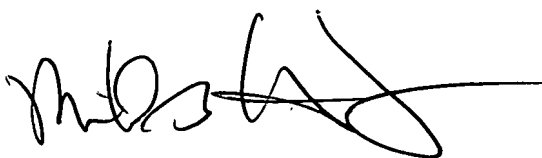
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MP Young

Micah-Paul Young
Examiner
Art Unit 1618


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER